

INSTRUCTIONS FOR USE

RADA® Embryo Transfer Catheter

Device Description

The RADA® Embryo Transfer Catheter is a sterile, single-use device intended for atraumatic embryo transfer during assisted reproductive procedures.

The device consists of an outer guide catheter and a soft inner transfer catheter designed to facilitate smooth and accurate embryo placement within the uterine cavity. The flexible catheter construction and soft distal tip help minimize trauma to the cervix and endometrium.

Graduation marks on the inner catheter provide insertion depth guidance. The device may be used under transabdominal ultrasound guidance for improved placement accuracy.

The catheter is manufactured from biocompatible medical-grade materials and is supplied sterile.

Intended Use

The RADA® Embryo Transfer Catheter is intended for the atraumatic transfer of embryos into the uterine cavity during in vitro fertilization (IVF) and related assisted reproductive technology (ART) procedures.

Indications for Use

The device is indicated for embryo transfer procedures following embryo culture during IVF and related ART treatments.

Contraindications

Do not use the device in patients with:

- Active pelvic infection;
- Active sexually transmitted disease;
- Severe cervical stenosis preventing safe catheter passage;
- Known uterine perforation;

- Any condition in which embryo transfer is contraindicated according to physician judgment.
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Warnings

- Use only by physicians trained and experienced in assisted reproductive techniques.
 - Maintain aseptic technique throughout the procedure.
 - Do not use if the package is opened, damaged, or beyond the expiration date.
 - Reuse, reprocessing, or resterilization may compromise device integrity and increase the risk of contamination or infection.
 - Excessive force during insertion may result in cervical or uterine injury.
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Precautions

- Manipulate the catheter gently to minimize trauma.
 - Minor bleeding or spotting may occur following cervical passage.
 - Infection may occur due to bacterial contamination during vaginal manipulation.
 - This device is intended for single use only.
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Instructions for Use

1. Open the sterile package using aseptic technique.
 2. Prepare and load the catheter according to the embryo transfer protocol of the IVF laboratory.
 3. Introduce the guide catheter through the cervical canal.
 4. Advance the inner transfer catheter to the desired intrauterine position.
 5. Transfer the embryos with or without ultrasound guidance, according to physician preference.
 6. Carefully withdraw the catheter following embryo transfer.
 7. Inspect the catheter to confirm absence of retained embryos.
 8. Discard the device after use.
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Potential Adverse Events

Potential adverse events associated with embryo transfer procedures may include:

- Cervical bleeding or spotting;
- Uterine cramping;

- Infection;
 - Vasovagal reaction;
 - Difficulty in catheter passage;
 - Cervical trauma;
 - Uterine perforation (rare).
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Sterility

- Sterilized using Ethylene Oxide (EO).
 - Sterile unless the package is opened or damaged.
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Storage Conditions

Store in a clean and dry environment away from direct sunlight, excessive heat, and humidity.

Disposal

Dispose of the device after use in accordance with applicable local regulations for biohazardous medical waste.
